

DETAILED ACTION

1. The amendment filed, 02/28/2011, is acknowledged. Claim 1 was amended. Claims 1-15 are pending in this application.

Election/Restrictions

2. Applicant's election of the species of a peptide of formula (I) wherein R is an isoalkyl group having 11 carbon atoms and X is a leucine in the reply filed on August 20, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A search was conducted for the elected species. During the course of the search, prior art was found that disclosed the genus of claim 3. Accordingly, the all of the species taught in the prior art that read on the genus of claim 3 have been applied. The election of species IS NOT vacated however. This is because, while the prior art applied may disclose some members of the genus, the prior art does not disclose all of the members that belong the genus of "lipopeptide compound" as claimed in claim 1. Thus, the election of species is maintained.

Withdrawn Rejections

3. The rejection of claims 1-6, 8, 10, 12 and 14, rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (JP09-165320) in view of Yoneda et al. is hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yoneda et al. (WO99/62482) in view of Noda (JP07-304630) for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to cosmetic composition comprising a lipopeptide and a polyoxyethylene glyceryl ether fatty acid ester.

Yoneda et al. teaches cosmetic formulations comprising a lipopeptide that has low skin penetration and low skin irritation (see abstract). Specifically, the reference discloses a lipopeptide having a sequence corresponding to Formula I as claimed in claim 3 (see page 5 and 6 of the reference). The reference states that the lipopeptide has the effect of inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound (see page 6-7). The reference discloses the weight of the lipopeptide in an amount between .01 to 30% by weight (see page 7). The reference

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discloses that external cosmetic include skin milk, skin cream, foundation cream, massaging cream, cleansing cream, shaving cream, lotion, shampoo, hair tonic, hair dye (see page 14).

The reference discloses a milky lotion that contains as one of the agents within the composition Avocado oil (see page 59). The difference between the prior art and the instant claims is that the reference does not specifically teach the use of polyoxyethylene glycerl fatty acid.

However, Noda et al. teach that conventional cosmetics contain oils require two steps of washing since the oil utilized in the makeup is not readily removed (see page 3 of translation). The reference states that this can be avoided if the cosmetic composition contains polyoxyethylene glyceryl fatty acid ester (see page 4 of translation). When this is used, not only does the composition work as a cosmetic but also provides a foaming action that allows for the removal of the makeup in a single step fashion. The reference states that the composition containing the fatty acid ester has a high cleaning effect and has an excellent usability and feel (see page 10). The reference states that fatty acid ester can be either isostearic acid or oleic acid (See page 5). The composition can contain 1-80% of in the total weight of the composition (see page 5). The reference discloses that other agents can be added to the cosmetic such as polyhydric alcohol, propylene glycol, oil, paraffin, uv ray absorbent (see page 5). It would have been obvious, therefore, to use polyoxyethylene glycerly fatty acid ester in the cosmetic formulation of Yoneda because polyoxyethylene glyceryl fatty acid ester provides a composition that allows with a high cleaning effect and has an excellent usability and feel. The presence of polyoxyethylene glyceryl fatty removes the need to of a two step washing procedure to remove the makeup and avoid residual oil. There would have been reasonable expectation because Noda et al. teaches the presence of

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polyoxyethylene glyceryl fatty acid ester in cosmetic formulations such as lip stick, foundation, mascara etc. . . and Yoneda discloses the similar cosmetic formulations. Note that Yoneda discloses the presence of oil and wax in some of the cosmetic preparations. Thus, the claims are rendered obvious over the prior art.

With respect to the concentration ranges claimed, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See MPEP 2144.05. Here, the prior art disclose concentration ranges for the agent utilized. Thus, it would have been obvious to optimize and improve upon what is already generally known to find the optimum combination of percentages.

Response to Arguments

Applicants argue that the claimed cleansing cosmetic composition achieves unexpectedly superior results for improved washability and preservation of the cosmetic. Applicants argue that the Yoneda's product, based on the changes observed, implies and establishes poor preservation stability for a person having ordinary skill in the art. Applicants present such evidence in the form of a 132 declaration and photographic evidence showing the degree of separation. Applicants argue that MPEP 716.02(e) states that the Applicants are not required to compare the claimed invention with subject matter

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that does not exist in the prior art. Applicants assert that "Noda is silent about the stability effect (preventing separation) in regard to polyoxyethylene glyceryl fatty acid ester and thus one would not have had any reason to expect that effect when polyoxyethylene glyceryl fatty acid ester were added to Yoneda.

Applicant state that Example of Noda show that sample 1 using (polyoxyethylene (2o) glyceryl triisostearate alone tended to lack skin comfort. Applicants conclude that neither Noda nor Yoneda disclose or suggest excellent storage stability of the cosmetic composition of the present invention.

Applicants argue that the concentration of the lipopeptide is critical since "comparative example 3 and the cosmetic composition contain 10 mass % of sodium surfactin in comparative example 4 of the present invention showed changes in appearance in the storage stability test." Applicants state that the concentration is not taught in Yoneda et al and nothing within the reference establishes "[t]he effects of the present invention obtained by limiting the content of the lipopeptide compounds within the range of .1 to 5 mass %."

Applicants argue that the Guidelines on Stability Testing of Cosmetic Colipa/CTFA, 2004 establish that separation is considered a negative characteristic in the field. Applicants state that the guidelines establish a criteria of "color, odor and appearance, and changes in the container. This shows that the change in appearance has significance in the art."

Applicants arguments have been fully considered but have not been found persuasive.

First with respect to the allegations of unexpected results regarding separation, it still remains unclear how this is deemed an undesired property. Applicants state that the

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Applicants argue that the Guidelines on Stability Testing of Cosmetic Colipa/CTFA, 2004 establish a criteria of color, odor and appearance, and changes in the container. However, reviewing the guidelines submitted, nothing within the reference either implies or teaches that the separation observed by Applicants should be avoided. That is to say, the “appearance” taught in the guidelines is inclusive of the separation observed in Yoneda et al. and is indicative of stability. Applicants have just merely concluded that “appearance has significance in the art” without establishing that separation into two layers is significant in the art. While appearance may be significant towards stability, the record does not establish that separation into two distinct layers is significant towards stability. Until such evidence is provided, one cannot conclude that the separation of the composition in two layers is a direct correlation to instability of the formulation.

Applicants have argued the concentration of the lipopeptide is significant, specifically referring to example 3 and 4 of the instant application. However, example 3 and 4 differed in not only the concentration of the surfactin, but also concentration in the polyoxyethylene (20) glyceryl triisostearate and the presence of tricaprylate/tricaprate glycerin. Example 3 contained a contained polyoxyethylene (20) glyceryl triisostearate at a concentration of 15.4 whereas Example 4 contained 4.7. Moreover, Example 3 contains tricaprylate/tricaprate glycerin whereas as example 4 contain Tri-2-ethylhexanoate glycerin. Given the differences between the formulations, one could not conclude if the stability is attributed to the concentration or the addition of the other agents or concentration of other additives.

With respect to the unexpected results, if there are any, the MPEP states “[e]vidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the

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claims.” See MPEP 716.02(b). Applicants have compared the results obtained from Yoneda to the present invention. However, the closest prior art to applicants invention regarding stability is the disclosure of Noda. The stability of the formulation would not be a result of the peptide has the effect of inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound. The stability would be attributed to the other agents added in the cosmetic formulation, namely the hydrophobic portions of the composition. Noda's formulation containing polyoxyethylene glyceryl fatty acid ester and do not contain an oily portion. Thus, one would expect this formulation not to separate. Accordingly, the closes prior art that concerns stability is the Noda reference since it does not contain an oily phase. Thus, the comparison to Yoneda et al. does not establish unexpected results.

Finally, Applicants Declaration demonstrates that two layers were formed in the Yoneda formulation. First, it is unclear what formulation was tested in Yoneda since the Declaration does not identify which example formulation was utilized in the experiment referred to in the declaration. Secondly one would expect that the use of polyoxyethylene glyceryl fatty acid ester would result in a non-separating formulation. Many of the formulations taught in Yoneda et al. would be expect to separate given that many contain an oil component and an aqueous component. For example, the formulation taught in example 3 contain avagado oil, in example 4 the formulation contain castor oil, etc... Thus, each one of these composition would be expected to separate given the hydrophilic and hydrophobic components in each formulation. The teachings of Noda state that the oil component can be replaced with the polyoxyethylene glyceryl fatty acid ester. Noda et al. teach that conventional cosmetics contain oils require two steps of washing since the oil utilized in the

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makeup is not readily removed (see page 3 of translation). The reference states that this can be avoided if the cosmetic composition contains polyoxyethylene glyceryl fatty acid ester (see page 4 of translation). When this is used, not only does the composition work as a cosmetic but also provides a foaming action that allows for the removal of the makeup in a single step fashion. When polyoxyethylene glyceryl fatty acid ester is present, one would expect the formulation not to separate since this is an amphiphilic emulsifier. When present by itself and not with an oily component, an homogenous mixture would be obtained. When present with oils, one would expect this agent to emulsify the formulation. Thus, if one were to use polyoxyethylene glyceryl fatty in the formulation, one would expect a lack of separation of two phases. Applicants are, however, invited to demonstrate that the separation observed in Yoneda et al. was also observed in the formulations of Noda et al.

Applicants have stated that Noda tended to lack skin comfort in example 1. However, it is unclear where this is taught. The prior art in example 1 emphasizes over and over that the formulation had great foamability and excelled in admiration.

Rejection is maintained.

5. Claims 1-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. (JP2000136114) in view of Yoneda et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to cosmetic composition comprising a lipopeptide and a polyoxyethylene glyceryl ether fatty acid ester.

Saka et al. teaches cleansing cosmetic formulations that contain that drops the charge of face make up with high water resisting property (see page 2). The reference disclose

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formulations containing N-acyl glutamic acid diester as the active agent in the composition. The reference also states that in the cleansing formulation other agents such as bees wax, jojoba oil, non ionic surface agent such as polyoxyethylene fatty acid esters, and multivalent alcohol ester antiseptics can be used (see page 5). Specifically, the reference discloses a water-in-oil cleansing cream formulation that contains paraffin 40%wt, hydrogenated tallow 2 %wt, sorbitan sesquioleate 1.4 %, polyoxyethylene stearate 1.5 %, polyoxyethylene glyceryl isostearate 1.3 %, behenyl alc. 1 %, paraben 0.5 %, Eldew CL 202 (N-lauroylglutamic acid cholesteryl octyldodecyl ester) 5 %, 1,3-butanediol 3 %, glycerin 2.5 %, and H₂O 41.8% (see abstract and example 1 on page 5). Note that the formulation contains polyoxyethylene glyceryl isostearate, which is the polyoxyethylene fatty acid ester and paraben. The difference between the prior art and the instant application is that the reference does not teach the use of a lipopeptide as claimed.

However, Yoneda et al. teaches cosmetic formulations comprising a lipopeptide that has low skin penetration and low skin irritation (see abstract). Specifically, the reference discloses a lipopeptide having a sequence corresponding to Formula I as claimed in claim 3 (see page 5 and 6 of the reference). The reference states that the lipopeptide has the effect of inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound (see page 6-7). The reference discloses the weight of the lipopeptide in an amount between .01 to 30% by weight (see page 7). The reference discloses that external cosmetics include skin milk, skin cream, foundation cream, massaging cream, cleansing cream, shaving cream, lotion, shampoo, hair tonic, hair dye (see page 14). It would have been obvious, therefore, to formulate the composition of Sakai et al. with the lipopeptide of Yoneda because the presence of lipopeptide has the effect of

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inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound. Note that Sakai et al. teaches a specific formulation with paraben. There would have been a reasonable expectation of success because Yoneda et al. teaches that the lipopeptide can be formulated into cosmetic cleaning compositions. Thus, the claims are rendered obvious.

With respect to the concentration ranges claimed, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See MPEP 2144.05. Here, the prior art disclose concentration ranges for the agent utilized. Thus, it would have been obvious to optimize and improve upon what is already generally known to find the optimum combination of percentages.

Response to Arguments

Applicants raise similar points to Yoneda et al. as raised in the rejection for Yoneda et al. (WO99/62482) in view of Noda (JP07-304630). Applicants argue that Sakai et al. does not disclose or suggest the superior effects of the present

Applicants arguments have been fully considered but have not been found persuasive.

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First with respect to the allegations of unexpected results regarding separation, it is still remains unclear how this is deemed an undesired property. Applicants state that the Applicants argue that the Guidelines on Stability Testing of Cosmetic Colipa/CTFA, 2004 establish a criteria of color, odor and appearance, and changes in the container. However, reviewing the guidelines submitted, nothing within the reference either implies or teaches that the separation observed by Applicants should be avoided. That is to say, the “appearance” that Applicants are relying upon to establish stability is inclusive of the separation observed in Yoneda et al. Applicants have just merely concluded that “appearance has significance in the art” without establishing that separation into two layers is significant in the art. While appearance may be significant towards stability, the record does not establish that separation into two distinct layers is significant towards stability. Until such evidence is provided, one cannot conclude that the separation of the composition in two layers is a direct correlation to instability of the formulation.

Applicants have argued the concentration of the lipopeptide is significant, specifically referring to example 3 and 4 of the instant application. However, example 3 and 4 differed in not only the concentration of the surfactin, but also concentration in the polyoxyethylene (20) glyceryl triisostearate and the presence of tricaprlyate/tricaprate glycerin. Example 3 contained a contained polyoxyethylene (20) glyceryl triisostearate at a concentration of 15.4 whereas Example 4 contained 4.7. Moreover, Example 3 contains tricaprlyate/tricaprate glycerin whereas as example 4 contain Tri-2-ethylhexanoate glycerin. Given the differences between the formulations, one could not conclude if the stability is attributed to the concentration or the addition of the other agents or concentration of other additives.

With respect to the unexpected results, if there are any, the MPEP states “[e]vidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims.” See MPEP 716.02(b). Applicants have compared the results obtained from Yoneda to the present invention. However, the closest prior art to applicants invention regarding stability is the disclosure of Saakai et al. This primary reference teaches all formulations containing polyoxyethylene glyceryl isostearate, which is the polyoxyethylene fatty acid ester and paraben. The only addition taught by Yoneda is the lipopeptide. Thus, a comparison for stability should be based on Sakai et al. and not Yoneda. Absent such evidence, one cannot conclude if the separation observed is unexpected.

Finally, applicants Declaration demonstrates that two layers were formed in the Yoneda formulation. First, it is unclear what formulation was tested in Yoneda since the Declaration does not identify which example formulation was utilized in the experiment referred to in the declaration. Secondly one would expect that the use of polyoxyethylene glyceryl fatty acid ester would result in a non-separating formulation. Many of the formulations taught in Yoneda et al. would be expect to separate given that many contain an oil component and an aqueous component. For example, the formulation taught in example 3 contain avagado oil, in example for the formulation contain castor oil, etc... Thus, each one of these composition would be expected to separate given the hydrophilic and hydrophobic components in each formulation. The teachings of Noda state that the oil component can be replaced with the polyoxyethylene glyceryl fatty acid ester. Noda et al. teach that conventional cosmetics contain oils require two steps of washing since the oil utilized in the makeup is not readily removed (see page 3 of translation). The reference

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states that this can be avoided if the cosmetic composition contains polyoxyethylene glyceryl fatty acid ester (see page 4 of translation). When this is used, not only does the composition work as a cosmetic but also provides a foaming action that allows for the removal of the makeup in a single step fashion. When polyoxyethylene glyceryl fatty acid ester is present, one would expect the formulation not to separate since this is an emulsifier. When present by itself and not with an oily component, an homogenous mixture would be obtained. When present with oils, one would expect this agent to emulsify the formulation. Thus, if one were to use polyoxyethylene glyceryl fatty in the formulation, one would expect a lack of separation of two phases.

The rejection is maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANISH GUPTA whose telephone number is (571)272-0965.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654